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Re-evaluation Decision

RVD2010-01

# Simazine

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## Re-evaluation Decision

After a re-evaluation of the herbicide simazine, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing simazine for sale and use in Canada.

An evaluation of available scientific information found that products containing simazine do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of simazine uses, new risk-reduction measures must be included on the labels of all products. No additional data are required at this time.

The regulatory approach for the re-evaluation of simazine was first presented in Proposed Re-evaluation Decision PRVD2009-12, *Simazine*, a consultation document.<sup>1</sup> This Re-evaluation Decision<sup>2</sup> describes this stage of PMRA's regulatory process for the re-evaluation of simazine, as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2009-12. To comply with this decision, registrants of products containing simazine will be informed of the specific requirements affecting their product registration(s).

## What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Simazine, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED). For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

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<sup>1</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>2</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of simazine. In this decision, the PMRA took into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy).

The USEPA re-evaluated simazine and published its conclusions in a 2006 Reregistration Eligibility Decision.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2009-12, *Simazine*.

## **What Is Simazine?**

Simazine is a selective systemic herbicide that is used to control germinating annual grasses and broad-leaved weeds on a variety of crops. In addition, simazine is used in shelterbelts, nursery stocks, woody ornamentals, woodlots, woodland and Christmas tree plantations, and site preparation for conifer planting. Simazine is also currently registered in Canada for "total" vegetation control in residential, agricultural and industrial non-crop areas such as patios, tennis courts, walls, paths, parking areas, and similar areas. However, this use is being voluntarily discontinued by registrants.

Simazine is applied by farm workers and professional applicators using ground equipment. Airblast equipment is also a registered application method, but only for woodland and Christmas tree plantations.

## **Health Considerations**

### **Can Approved Uses of Simazine Affect Human Health?**

**Simazine is unlikely to affect your health when used according to the revised label directions.**

People could be exposed to simazine through consumption of food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that simazine was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

## Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Simazine is currently registered in Canada for use on apples, pears, loganberries, raspberries (red), grapes, asparagus, corn (field and sweet), strawberries, apricots, blackberries, cherries, filberts, hazelnuts, blueberries, peaches and plums, and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for simazine in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

## Environmental Considerations

### What Happens When Simazine Is Introduced Into the Environment?

**Simazine is unlikely to affect non-target organisms when used according to the revised label directions.**

Terrestrial and aquatic species could be exposed to simazine in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some potential risks of concern.

The USEPA concluded that the reregistration of simazine was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required. Furthermore, the PMRA requires aquatic and terrestrial buffer zones for simazine to protect aquatic organisms and non-target terrestrial plants from spray drift.

## Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of simazine, the PMRA is requiring further risk-reduction measures for product labels.

### Human Health

- Additional protective equipment to protect mixer/loader/applicators
- A restricted-entry interval to protect workers re-entering treated sites
- Changes to maximum application rates on corn and strawberries, and to the number of yearly applications for strawberries
- Advisory label statement regarding the method of application on fruit and nut crops
- Buffer zones from wells, lakes, reservoirs, and intermittent streams and rivers to protect drinking water
- Restrictions regarding the application of simazine in fields containing tile drainage systems
- The formulation of simazine end-use products into wettable powders is prohibited.

### Environment

- Precautionary statements and buffer zones to protect non-target terrestrial and aquatic habitats that may contain sensitive species
- Additional groundwater and runoff advisory label statements

### Other Information

Any person may file a notice of objection<sup>3</sup> regarding this decision on simazine within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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<sup>3</sup> As per subsection 35(1) of the *Pest Control Products Act*.